REMARKS

The specification has been amended to update the status of related applications.

The Examiner objected to claims 29 and 31 apparently because they are multiple dependent claims. The Examiner cited 37 C. F. R. § 1.75(c) and MPEP § 608.01(n).

37 C. F. R. § 1.75(c) provides:

> "(c) One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. *Any dependent claim which refers to more than one other claim ('multiple dependent claim') shall refer to such other claims in the alternative only. * * * A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered.*" Italics Applicants'.

MPEP § 608.01(n) provides, in pertinent part:

> "*The second paragraph of 35 U. S. C. 112 has been revised in view of the multiple dependent claim practice introduced by the Patent Cooperation Treaty. Thus 35 U. S. C. 112 authorizes multiple dependent claims in applications filed on and after January 24, 1978* as long as they are in the alternative form (e. g., 'A machine according to claims 3 or 4, further comprising -- - ')." Italics Applicants'.

It is clear that, contrary to what appears to be the Examiner's position, multiple dependent claims are specifically permitted by the Rules of Practice in Patent Cases. Accordingly, Applicants request withdrawal of the Examiner's apparently erroneous objection to multiple dependent claims 29 and 31.

The Examiner rejected claims 1-32 under 35 U. S. C. § 102. The Examiner relied upon Brown U. S. Patent 5,307,263 (hereinafter Brown) to support this rejection.

Brown explains the following about his blood glucose monitor 16, the only "hand-held instrument for determining the concentration of a medically significant component of a body fluid or a control" (to quote independent claim 1 of the present application) in Brown:

> "A modular self-care health monitoring system which employs a small handheld microprocessor-based unit (12) such as a compact video game system of the type that includes a display screen (28), switches for controlling device operation (30,32,34,36,38) and a program cartridge (41,42,43) that is inserted into the handheld unit to adapt it for operation with a microprocessor-based healthcare data management unit (10) and *a glucose monitor (16)* (or, another type of health monitor 30,32). A modem (46), included in the microprocessor-based

data management unit (10), allows data such as blood glucose level to be transmitted to a clearinghouse (54), which transmits reports to a remotely located healthcare professional (60) via facsimile transmission (55). The system is intended for use by persons of all ages, but primarily is directed to children afflicted with diabetes or other chronic ailments." Brown's abstract, italics Applicants'.

"*A data port may be provided that allows test results stored in the memory of the microprocessor-based blood glucose monitoring system to be transferred to a data port (e.g., RS-232 connection) of a personal computer or other such device for subsequent analysis.*" Brown, col. 2, lines 34-39, italics Applicants'.

"*Some currently available blood glucose monitoring systems provide a data port that can be interconnected with and transfer data to a personal computer (e.g., via an RS-232 connection).* With such a system and a suitable programmed computer, the user can generate and display trend information or other data that may be useful in administering his or her treatment plan. *Moreover, in such systems, data also can be transferred from the blood glucose monitoring system to a healthcare professional's computer either directly or remotely by telephone if both the blood glucose monitoring system (or computer) to which the data has been downloaded and the healthcare professional's computer are equipped with modems.* Although such a data transfer provision allows a healthcare professional to analyze blood glucose data collected by a diabetic, this aspect of currently available blood glucose monitoring systems has not found widespread application. First, the downloading and subsequent analysis feature can only be used by system users that have ready access to a computer that is programmed with appropriate software and, in addition, have both the knowledge required to use the software (and the inclination to do so). This same problem exists with respect to data transfer to (and subsequent analysis by) a healthcare professional. Moreover, various manufacturers of systems that currently provide a data transfer feature do not use the same data format. Therefore, if a healthcare professional wishes to analyze data supplied by a number of different blood glucose monitoring systems, he or she must possess software for each of the systems and must learn to conduct the desired analyses with each software system." Brown, col. 3, line 49-col. 4, line 12, italics Applicants'.

"[T]he invention includes a microprocessor-based healthcare data management unit, a program cartridge and a monitoring unit. When inserted in the handheld microprocessor unit, the program cartridge provides the software necessary (program instructions) to program the handheld microprocessor unit for operation with the microprocessor-based data management

unit. Signal communication between the data management unit and the handheld microprocessor unit is established by an interface cable. *A second interface cable can be used to establish signal communication between the data management unit and the monitoring unit or, alternatively, the monitoring unit can be constructed as a plug-in unit having an electrical connector that mates with a connector mounted within a region that is configured for receiving the monitoring unit.*" Brown, col. 5, lines 10-26, italics Applicants'.

"FIG. 1 depicts a self-care health monitoring system arranged in accordance with the invention. In the arrangement shown in FIG. 1, a data management unit 10 is electrically interconnected with a handheld microprocessor-based unit 12 via a cable 14. In the depicted arrangement, *data management unit 10 also is electrically interconnected with a blood glucose monitor 16 of the type capable of sensing blood glucose level and producing an electrical signal representative thereof.* Although FIG. 1 illustrates blood glucose monitor 16 as being connected to data management unit 10 by a cable 18, it may be preferable to construct blood glucose monitor 16 as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit 10. Regardless of the manner in which blood glucose monitor 16 is interconnected with data management unit 10, both that interconnection and cable 14 are configured for serial data communication between the interconnected devices.

"*Also shown in FIG. 1 are two additional monitoring devices 20 and 22, which are electrically connected for serial data communication with data management unit 10 via cables 24 and 26, respectively. Monitoring units 20 and 22 of FIG. 1 represent devices other than blood glucose monitor 16 that can be used to configure the invention for self-care health monitoring applications other than (or in addition to) diabetes care. For example, as is indicated in FIG. 1, the monitoring device 20 can be a peak-flow meter that provides a digital signal representative of the airflow that results when a person suffering from asthma or another chronic respiratory affliction expels a breath of air through the meter. As is indicated by monitor 22 of FIG. 1, various other devices can be provided for monitoring conditions such as blood pressure, pulse, and body temperature to thereby realize systems for self-care monitoring and control of conditions such as hypertension, certain heart conditions and various other afflictions and physical conditions*. Upon understanding the hereinafter discussed aspects and features of the invention it will be recognized that the invention is easily implemented for these and other types of healthcare monitoring. In particular, *monitors used in the practice of the invention can be arranged in a variety of ways as long as the data to be recorded or otherwise employed by*

handheld microprocessor unit 12 and/or data management unit 10 is provided in serial format in synchronization with clock signals provided by data management unit 10. As is the case with blood glucose monitor 16, the additional monitors can be configured as plug-in units that are directly received by data management unit 10, or can be connected to data management unit 10 with cables (as shown in FIG. 1)." Brown, col. 7, line 29-col. 8, line 13, italics Applicants'.

"*Depending upon the operational mode selected by the user, data is supplied to data management unit 10 by blood glucose monitor 16, by additional monitors (20 and 22 in FIG. 1) or any interconnected computers or data processing facility* (such as the hereinafter described user's computer 48 and clearinghouse 54 of FIG. 1). During such operation, mode switches 30, 32, 34, 36 and 38 are selectively activated so that signals are selectively coupled to the video game system (handheld microprocessor unit 12) and processed in accordance with program instructions stored in program cartridge 42. The signal processing performed by handheld microprocessor unit 12 results in the display of alphanumeric, symbolic, or graphic information on the video game display screen (i.e., display unit 28 in FIG. 1), which allow the user to control system operation and obtain desired test results and other information." Brown, col. 10, lines 8-25, italics Applicants'.

"Regardless of whether a compact video game system, another type of commercially available handheld microprocessor-based unit, or a specially designed unit is used, *the preferred embodiments of FIG. 1 provide a self-care blood glucose monitoring system in which program cartridge 42: (a) adapts handheld microprocessor unit 12 for displaying instructions for performing the blood glucose test sequence and associated calibration and test procedures; (b) adapts handheld microprocessor unit 12 for displaying (graphically or alphanumerically) statistical data such as blood glucose test results taken during a specific period of time (e.g., a day, week, etc.); (c) adapts handheld microprocessor unit 12 for supplying control signals and signals representative of food intake or other useful information to data management unit 10; (d) adapts handheld microprocessor unit 12 for simultaneous graphical display of blood glucose levels with information such as food intake; and, (e) adapts handheld microprocessor unit 12 for displaying information or instructions from a healthcare professional that are coupled to data management unit 10 from a clearinghouse 54.* The manner in which the arrangement of FIG. 1 implements the above-mentioned functions and others can be better understood with reference to FIGS. 2 and 3." Brown, col. 11, lines 40-64, italics Applicants'.

"FIG. 3 illustrates the manner in which data management unit 10 is arranged and interconnected with other system

components for effecting the above-described operational aspects of the invention and additional aspects that are described relative to FIGS. 4-10. As is symbolically indicated in FIG. 3, handheld microprocessor unit 12 and blood glucose monitor 16 are connected to a dual universal asynchronous receiver transmitter 70 (e.g., by cables 14 and 18 of FIG. 1, respectively). As also is indicated in FIG. 3 when a system user connects a personal computer 48 (or other programmable digital signal processor) to data port 44, signal communication is established between personal computer 48 and a second dual universal asynchronous receiver transmitter 72 of data management unit 10. Additionally, dual universal asynchronous receiver transmitter 72 is coupled to modem 46 so that data communication can be established between data management unit 10 and a remote clearinghouse 54 of FIGS. 1 and 2.

"Currently preferred embodiments of data management unit 10 include a plurality of signal sensors 74, with an individual signal sensor being associated with each device that is (or may be) interconnected with data management unit 10. As previously discussed and as is indicated in FIG. 3, these devices include handheld microprocessor unit 12, blood glucose monitor 16, personal computer 48, remote computing facility 54 and, in addition, peak-flow meter 20 or other additional monitoring devices 22. Each signal sensor 74 that is included in data management unit 10 is electrically connected for receiving a signal that will be present when the device with which that particular signal sensor is associated is connected to data management unit 10 and, in addition, is energized (e.g., turned on). For example, in previously mentioned embodiments of the invention in which data port 44 is an RS-232 connection, the signal sensor 74 that is associated with personal computer 48 can be connected to an RS-232 terminal that is supplied power when a personal computer is connected to data port 44 and the personal computer is turned on. In a similar manner, the signal sensor 74 that is associated with clearinghouse 54 can be connected to modem 46 so that the signal sensor 74 receives an electrical signal when modem 46 is interconnected to a remote computing facility (e.g., clearinghouse 54 of FIG. 2) via a telephone line 50." Brown, col. 15, line 44-col. 16, line 23.

"[I]n the currently preferred embodiments of the invention, *blood glucose monitor 16 operates in conjunction with data management unit 10 and handheld microprocessor unit 12 to: (a) perform a test or calibration sequence in which test are performed to confirm that the system is operating properly; and, (b) perform the blood glucose test sequence in which blood glucose meter 16 senses the user's blood glucose level.* Suitable calibration procedures for blood glucose monitors are known in the art. For example, blood glucose monitors often are supplied with a 'code strip,' that is inserted in the monitor

and results in a predetermined value being displayed and stored in memory at the conclusion of the code strip calibration procedure. When such a code strip calibration procedure is used in the practice of the invention, the procedure is selected from one of the system menus. For example, if the system main menu includes a 'monitor' menu item, a submenu displaying system calibration options and an option for initiating the blood glucose test may be displayed when the monitor menu item is selected. When a code strip option is available and selected, a sequence of instructions is generated and displayed by display screen 28 of handheld microprocessor unit 12 to prompt the user to insert the code strip and perform all other required operations. At the conclusion of the code strip calibration sequence, display unit 28 of handheld microprocessor unit 12 displays a message indicating whether or not the calibration procedure has been successfully completed. For example, FIG. 4 illustrates a screen display that informs the system user that the calibration procedure was not successful and that the code strip should be inserted again (i.e., the calibration procedure is to be repeated). As is indicated in FIG. 4, display screens that indicate a potential malfunction of the system include a prominent message such as the 'Attention' notation included in the screen display of FIG. 4.

"As previously indicated, the blood glucose test sequence that is employed in the currently preferred embodiment of the invention is of the type in which a test strip is inserted in a receptacle that is formed in the blood glucose monitor. A drop of the user's blood is then applied to the test strip and a blood glucose sensing sequence is initiated. When the blood glucose sensing sequence is complete, the user's blood glucose level is displayed.

"*In the practice of the invention, program instructions stored in data management unit 10 (e.g., system ROM 90 of FIG. 3) and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 cause the system to display step-by-step monitoring instructions to the system user and, in addition, preferably result in display of diagnostic messages if the test sequence does not proceed in a normal fashion. Although currently available self-contained microprocessor-based blood glucose monitors also display test instruction and diagnostic messages, the invention provides greater message capacity and allows multi-line instructions and diagnostic messages that are displayed in easily understood language rather than cryptic error codes and abbreviated phraseology that is displayed one line or less at a time. For example, as is shown in FIG. 5, the complete results of a blood glucose test (date, time of day, and blood glucose level in milligrams per deciliter) can be concurrently displayed by display screen 28 of handheld microprocessor unit 12 along with an instruction to*

remove the test strip from blood glucose monitor 16. As previously mentioned, when the blood glucose test is complete, the time and date tagged blood glucose test result is stored in the memory circuits of data management unit 10 (e.g., stored in EEPROM 94 of FIG. 3)." Brown, col. 17, line 14-col. 18, line 18, italics Applicants'.

"1. A self-care health monitoring system comprising: a programmable microprocessor-based unit, said programmable microprocesses-based unit including a display screen and a plurality of switches, said microprocessor-based unit including a receptacle for receiving a program cartridge that includes a memory circuit having stored therein program instructions for controlling the operation of said programmable microprocessor-based unit; *monitoring means operable for sensing a condition indicative of a person's physical well-being and for producing digitally encoded signals representative of said condition*; and *a microprocessor-based data management unit connectable in signal communication with both said programmable microprocessor-based unit and said monitoring means, said microprocessor-based data management unit including a central processing unit* and a memory circuit, said memory circuit for storing program instructions for controlling the operation of said central processing unit, *said central processing unit being responsive to program instructions stored in said memory circuit of said microprocessor-based data management unit for processing said digitally encoded signals supplied by said monitoring means that are representative of said sensed condition, said central processing unit of said data management unit supplying signals representative of said sensed condition to said programmable microprocessor-based unit in response to digitally encoded signals that are supplied to said data management unit by said programmable microprocessor-based unit* upon selective operation of at least one of said switches of said programmable microprocessor unit." Brown's claim 1, italics Applicants'.

"4. The self-care health monitoring system of claim 3 further comprising a clearinghouse facility for receiving said signals supplied via said modem of said microprocessor-based data management unit, said clearinghouse facility being remotely located from said microprocessor-based data management unit and including digital signal processing means for *converting said digitally encoded signal supplied via said modem of said microprocessor-based data management unit into a report that provides information relating to said condition sensed by said monitoring means*, said signal processing means of said clearinghouse facility for transmitting a facsimile signal representative of said report to said remotely located healthcare professional." Brown's claim 4, italics Applicants'.

"5. The self-care health monitoring system of claim 2 wherein

said monitoring means is a blood glucose monitor that produces digitally encoded signals representative of a user's blood glucose level when a sample of the user's blood is deposited on a reagent impregnated region of a test strip that is inserted into a receptacle that is included in said blood glucose monitor." Brown's claim 5, italics Applicants'.

"7. The self-care health monitoring system of claim 6 further comprising a clearinghouse facility for receiving said signals supplied via said modem of said microprocessor-based data management unit, said clearinghouse facility being remotely located from said microprocessor-based data management unit and including digital signal processing means for *converting said digitally encoded signal supplied via said modem of said microprocessor-based data management unit into a report that provides information relating to said condition sensed by said monitoring means*, said signal processing means of said clearinghouse facility for transmitting a facsimile signal respesentative of said report to said remotely located healthcare professional." Brown's claim 7, italics Applicants'.

"11. The self-care health monitoring system of claim 10 further comprising a clearinghouse facility for receiving said signals supplied via said modem of said microprocessor-based data management unit, said clearinghouse facility being remotely located from said microprocessor-based data management unit and including digial signal processing means for *converting said digitally encoded signal suppled via said modem of said microprocessor-based data management unit into a report that provides information relating to said condition sensed by said monitoring means*, said signal processing means of said clearinghouse facility for transmitting a facsimile signal representative of said report to said remotely located healthcare professional." Brown's claim 11, italics Applicants'.

Nowhere do any of the extensive above-quoted passages from Brown disclose or suggest present claim 1's specifically recited

"method of configuring a hand-held instrument for determining the concentration of a medically significant component of a body fluid or a control, the method comprising the steps of providing a configuring computer having a first port for transmitting at least one of instructions and data for configuring the instrument, providing on the instrument a second port for receiving said at least one of instructions and data from the configuring computer, coupling said first port to said second port, transmitting said one of instructions and data to configure said instrument from said first port, receiving said one of instructions and data at said second port, and configuring said instrument according to said one of instructions and data transmitted from said first port and received at said second port."

All of claims 2-32 depend from claim 1 and thus incorporate the above language of claim 1 by reference. This language, which is neither disclosed nor suggested by Brown thus distinguishes claims 2-32 from Brown as well, at least for this reason. The 35 U. S. C. § 102 rejection of claims 1-32 based upon Brown is thus overcome.

Accordingly, Applicants submit that claims 1-32 are in condition for further favorable consideration, culminating in allowance. Such action is respectfully requested.

Applicants point out to the Examiner that documents received so far in this application do not indicate consideration by the Examiner of the prior art submitted with this application upon entry into the national phase. For the Examiner's convenience in indicating that the Examiner has considered this prior art, a form PTO-1449 is submitted herewith upon which the Examiner can indicate consideration of this prior art. So that there is no misunderstanding about the timeliness of the submission of this prior art, Applicants also enclose a copy of the form PCT/DO/EO/905 highlighted where the form indicates that this art was in fact received by the Patent Office.

The Commissioner is hereby authorized to charge any fees which may be due to constitute this a timely response to the June 8, 2004 official action to Applicants' undersigned counsel's deposit account 10-0435 with reference to file number 5727-65998. A duplicate copy of this authorization is enclosed for that purpose.

Respectfully submitted,

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INDS02 RDC 676753

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 5727-65998	SERIAL No. 09/555,718
	APPLICANT Batman et al.	
	FILING DATE January 12, 2001	GROUP 2142

U.S. PATENT DOCUMENTS

*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	AA	5,361,336	Nov. 1, 1994	Atchison			
	AB	5,606,164	Feb. 25, 1997	Price			
	AC	5,619,991	April 15, 1997	Sloane			
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	AH	5,735,285	April 7, 1998	Albert			
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	AJ	4,696,309	Sept. 29, 1987	Stephan			
	AK	4,383,534	May 17, 1983	Peters			

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes No
	AL						
	AM						
	AN						
	AO						
	AP						

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AR	
	AS	
	AT	
	AU	
	AV	
	AW	
	AX	
	AY	
	AZ	

Examiner	Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.
Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

BASED ON FORM PTO 1449